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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/898,726	07/03/2001	Russell A. Houser	509192000220	4439

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EXAMINER

FARAH, AHMED M

ART UNIT	PAPER NUMBER
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3739

DATE MAILED: 02/26/2003

#12

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.
09/898,726

Applicant(s)
Houser et al.

Examiner
A. Farah

Art Unit
3739

MF

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE three MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on Dec 6, 2002
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-97 is/are pending in the application.
- 4a) Of the above, claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 76-97 is/are allowed.
- 6) ☒ Claim(s) 1-3, 5, and 7-75 is/are rejected.
- 7) ☒ Claim(s) 4 and 6 is/are objected to.
- 8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
*See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☒ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s). 11 6) ☐ Other: _____

Art Unit: 3739

DETAILED ACTION

Response to Amendment

1. In a telephone interview with the Applicant's attorney, Johney Han, on December 12, 2002, the U.S. Patent No. 6,269,819 B1 to Oz et al. was discussed in view of the pending claims. As a result, the Applicant's attorney has proposed new amendments to claims 1 and 47. However, the suggested changes are not filed as of the date of this Office Action.

Claim Rejections - 35 USC § 102

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371© of this title before the invention thereof by the applicant for patent.

3. Claims 1-3, 5, 7-17, 24-36, 41, 42, and 47-68 are rejected under 35 U.S.C. 102(e) as being anticipated by Oz et al. U.S. Patent No. 6,269,819 B1.

As to claims 1-3, 5, 7-9, 15, 29, 33, 41, 47-51, 55, 57, 63, and 64, Oz et al. disclose method and apparatus for treating tissue near a cardiac valve to modify flow through the valve, the apparatus comprising: a cinching member having a central region and at least two anchoring regions on opposing ends of the central region, wherein each anchoring region is configured to be anchored to

Art Unit: 3739

opposing areas of tissue and urge the areas of tissue towards each other; the cinching member being further configured for delivery through a catheter to the tissue whereby the cinching member has a first shape during the delivery and a second shape after the delivery. See Figures 2 and 30.

As to claims 12-14, and 65, their cinching member is configured to approximate a portion of periphery defined by the valve as presently claimed.

As to claims 24-28 and 60-62, the central region of the cinching member defines a first plane (the plane perpendicular to the center of the cinching member) and the anchoring regions define a second plane. The second plane defines an angle relative to the first plane, wherein the magnitude of the angle relates the force applied to the cinching member. See Fig. 29.

As to claims 16, 17, 42, 53, and 54, their cinching member is a biocompatible material selected from the group consisting of shape memory Titanium alloy (Col. 5, lines 14-17).

As to claims 10, 11, 30-32, 52, 56, 58, and 59, the cinching member is selected from the group consisting of hooks, clips, screws, V-shapes, and U-shapes. See Figures 21-30.

As to claims 34, 36, 66, and 68, they use a guide wire (stylet) to advance the cinching member (Col. 6, lines 29-34).

Art Unit: 3739

Claim Rejections - 35 USC § 103

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

5. Claims 37 and 69 are rejected under 35 U.S.C. 103(a) as being unpatentable over Oz et al. in view of Muller U.S. Pat. No. 5,725,521.

Although Oz et al., described above, use sliding mechanism to advance and retract the guide wire (stylet), they do not particularly teach its type. Muller teaches an alternative heart modifying device and methods comprising a thumb-slide advancing mechanism. Thus, it would have been obvious to one skilled in the art at the time of the applicant's invention to modify the device of Oz et al. with Muller and use a thumb-slide as an alternative advancing mechanism. rejected under 35 U.S.C. 103(a) as being unpatentable over .

6. Claims 18-23, 38-40, 43-46, and 70-75 are rejected under 35 U.S.C. 103(a) as being unpatentable over Oz et al. in view of Crowley et al. U.S. Pat. No. 6,004,269.

02/24/03

Oz et al., described above, do not teach the use of therapeutic coating, radiopaque material selected from the group consisting of platinum, gold, etc., or an ultrasound sensor connected to a monitor for guiding the system as presently claimed.

Art Unit: 3739

However, Crowley et al. disclose an ultrasound guided catheter and method for modifying the flow through a cardiac valve, the device comprising: therapeutic agents; radiopaque markers; coating material selected from the group consisting of platinum and gold; and an ultrasound sensor disposed at the tip of the catheter device for monitoring the treatment and operations of the device. Thus, it would have been obvious to one skilled in the art at the time of the applicant's invention to modify Oz et al. with Crowley et al. to employ radiopaque markers and ultrasound sensors in order to monitor the operation of the system. It would have been further obvious to one skilled in the art at the time of the applicant's invention to use gold or platinum as an alternative coating material.

Allowable Subject Matter

7. Claims 4 and 6 are would be allowable if rewritten to overcome the rejection(s) under 35 U.S.C. 112, second paragraph, set forth in this Office action and to include all of the limitations of the base claim and any intervening claims.

8. Claims 76-97 are allowed. The prior art of record do not teach a treatment system for treating tissue near a valve to modifying flow through the valve, comprising: a catheter configured for transluminal delivery; an end effector in communication with the distal end of the catheter, the end effector being configured to transfer energy to a tissue at target site to induce thermal shrinkage of collagen in the tissue; and a cinching member configured to be anchored to opposing sides of the valve and urge the areas of the tissue towards one another, the cinching member being further configured for delivery through the catheter as presently claimed.

7/24/13

Art Unit: 3739

Conclusion

9. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CAR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CAR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to A. Farah whose telephone number is (703) 305-5787. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ms. Linda Dvorak, can be reached on (703) 308-0994. The fax number for the Examiner is (703) 746-3368.

A. M. Farah

Patent Examiner/(Art Unit 3739)



February 21, 2003



Linda C. M. Dvorak

Supervisory Patent Examiner